DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 8 2009

Radiancy (Israel) LTD.
c/o Boston MedTech Advisors, Inc.
Zvi Ladin, PhD, Principal
990 Washington Street, Suite 204
Dedham, MA 02026

Re: k082423
No! No! Skin™
Appeal of Not Substantially Equivalent Decision
Dated: December 18, 2008
Received: December 19, 2008

Dear Dr. Ladin:

This letter is in response to your letter of appeal dated December 18, 2008, requesting that the not substantially equivalent (NSE) decision for the above reference premarket notification submission (510(k)) that was issued on December 3, 2008, from Mark N. Melkerson, Director, Division of General, Restorative, and Neurological Devices (DGRND), now the Division of Surgical, Orthopedic, and Restorative Devices (DSORD), Office of Device Evaluation, be reviewed by the next level supervisor. I have reviewed this appeal under our regulations found in Title 21 of the Code of Federal Regulations Part 10.75 Internal agency review of decision, as the next level supervisor.

After reviewing your letter of appeal, including my review of the 510(k), meeting internally on several occasions with DSORD, and discussing your appeal with you and your clients on February 17, 2009, and consulting with my clinical deputy, I have determined that your device has performance that is substantially equivalent to predicate devices cleared for over-the-counter used in the treatment of mild to moderate acne. My decision is based on the fact that your 510(k) contained data from a randomized, sham-controlled, double-blinded, clinical trial demonstrating that your device provides a statistically and clinically significant improvement in the time to improvement and time to resolution of mild to moderate acne when compared to sham treatment, as assessed by blinded investigators. I have determined that these data are sufficient to provide a reasonable assurance of the safety and effectiveness of your device for the purposes of demonstrating substantial equivalence. Therefore, I am overturning the NSE decision from DSORD and issuing a letter of substantial equivalence (enclosed) for the above referenced device as described in the 510(k).

If you have any questions regarding this letter, please contact Heather S. Rosecrans, Chief, 510(k) Staff at (240) 276- 4021.

Sincerely yours,

Donna-Bea Tillman, Ph.D., M.P.A.
Director
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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Re: k082423
Trade/Device Name: No! No! Skin™
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in Dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: October 23, 2008
Received: October 24, 2008

Dear Dr. Ladin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Donna-Bea Tillman, Ph.D., M.P.A.
Director
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k082423

Device Name: No! No! Skin™

Indications For Use: No! No! Skin is indicated for the treatment of individual acne pimples in persons with mild to moderate inflammatory acne.

The product code is: GEX
Regulation number: 21 CFR 878.4810
Regulation name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory class: II

Prescription Use _____ AND/OR Over-The-Counter Use X
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)